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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,791	08/08/2001	David Hung	12.019011	9920

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/923,791	**Applicant(s)** HUNG, DAVID	
	Examiner Ulrike Winkler	**Art Unit** 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2,6-15 and 17-20*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Applicants' argument in the response is that the Love U.S. Pat No. 6,221,622 ('622) does not teach the use of a single lumen catheter. Applicants cite *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) for the position that in order to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. The Office adheres to this principle and finds that in the instant case all the claim limitations are met by the cited art. In this instant the '622 patent within the four corners of the document indicates that the prior art used a rigid cannula to obtain and retrieve fluid from the breast duct. Thus, Love and Barsky (1996) reference has been incorporate into the '622 patent by reference.

> Incorporation by Reference (MPEP 2163.07(b)): Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter.

There is nothing in the '622 patent or the incorporated Love and Barsky (1996) reference to indicate that the prior art used anything but a single lumen catheter. Thus applicants arguments that the '622 reference does not teach the use of a single elongated lumen is not persuasive.

In response to Applicants arguments regarding '622 reference, a reference is valid for all that it teaches. "Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments v. LKB Produkter AB*, 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). In this instance the '622 patent teaches the following:

> Prior attempts to obtain cellular material from individual breast ducts have been only partly successful. As reported by the inventor herein, in Love and Barsky (1996) *The Lancet* 348:997-999, breast ducts have been cannulated with a rigid cannula and instilled with very small volumes (0.2 ml to 0.5 ml) of saline. Saline was recovered separately

> through a capillary tube, and cellular material recovered from the saline. It was not clear, however, if cellular material was recovered from most or all portions of the ductal network. Unless such representative samples can be obtained, reliable diagnostics cannot be performed. While the paper proposes development of a two-lumen catheter, no such catheter or its use is described in the publication. (see '622, column 2, lines 8-20)

Thus the prior art referred to in the '622 patent only used a single lumen catheter.

The definition of a "catheter" is a tubular medical device for insertion into canals, vessels, passageways, or body cavities usually to permit injection or withdrawal of fluids or to keep passageway open (see Webster Dictionary 10th edition). Cannula and catheters are structurally equivalent in that they are both tubular devices used for insertion into a cavity, duct or vessel.

The definition of a "cannula" is a small tube for insertion into a body cavity or into a duct or vessel (see Webster Dictionary 10th edition). Thus a cannula qualifies as a "a single elongated lumen." The prior art disclosed and incorporated by reference in '622 makes use of a cannula to wash breast ducts and retrieve fluid. Therefore, Applicants argument that it is mere speculation by the Office that the '622 teaches a single lumen catheter is not convincing.

Applicants' other argument is that the Office cannot have it both ways. (see response page 8, 3rd paragraph). In response the final rejection made by the Office to applicants, the Office was not convinced by Applicants' arguments that "an elongated lumen" was referring to a single elongated lumen. The Office in the final rejection indicated that limitations from the specification are not read into the claim. Thus in order to clarify what is encompassed by Applicants' invention Applicant needed to amend the claims to indicate that only "a single elongated lumen" is contemplated in the instantly claimed invention. So on the point of "an

elongated lumen" the Office required that the claims be amended to include the limitation "single" in the body of the claims.

In the final action the Office indicated that the definition of "fluid" as presented in the specification is not limited to the liquid portion. Applicants are free to be their own lexicographer. However, once Applicants have chosen to define "fluid" as being something more than just liquid, Applicants use and definition is then applied by the Office in searching the prior art and applying the prior art. "The fluid from the breast duct can contain ductal epithelial cells, including cells of a stage considered to be precancerous or cancerous." (see instant specification page 6, lines 10-12). "Once ductal fluid is analyzed for one or more markers, the fluid may also be analyzed cytological to determine the cytological status of the ductal epithelial cells and other cells." (see instant specification page 7, lines 3-5). Based on the usage of what is encompassed by ductal fluid in the instant specification ductal "fluid" is not limited to the liquid portion but comprises cells from the breast duct as well. Thus the "ductal fluid sample" to be analyzed in the instantly claimed invention included cells (tissue). The King et al. reference uses nipple aspirate fluid (NAF) to asses cells found in the fluid for signs of malignancy (see King et al. abstract).

There is nothing inconsistent in the Offices use of the specification for the purpose of the claim interpretation. As far as the "single lumen catheter" is concerned, the "single" limitation needed to be inserted into the claim for the purpose of clarification. When more than one interpretation can apply to a claim it is Applicants responsibility to clearly and distinctly claim their invention. In this instance it would not be proper for the Office to read limitations from the specification into the claim. On the other hand where a term is defined in the specification such

as the term "fluid" which differs from the conventional use of the term then the definition found in the specification is applied for purposes of claim interpretation. Here there where two separate limitations in the claims that were treated differently for the reasons set out above. There is nothing consistent the treatment of the two separate and distinct limitations.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here Applicants argue that the Makita et al. reference does not "teach the use of a single lumen catheter to wash and collect fluid from a single breast duct. An endoscope is not a device capable of injecting ant then retrieving fluid from a breast duct." (see response page 8, 2nd paragraph). In the Makita et al. the outer cylinder (the single elongated lumen; comprising a disposable 16 gauge Surflo intravenous catheter) is placed into a single breast duct. Although the reference does not teach washing and removing fluid from the breast duct, the reference does teach collecting fluid from the duct. "After confirming that the lesion is inside the outer cylinder, we take out the endoscope and aspirate through the outer cylinder using an inserted syringe, so we can get the lesion, as a small tissue bit or fluid sample, inside the outer cylinder." (see Makita et al. page 181, column 1, 1st paragraph). Thus the reference was applied as teaching the use of a single elongated lumen to collect fluid sample form a single breast duct. Therefore, Applicants argument that the reference does not anticipate the instantly claimed invention is not persuasive, because in the instant case the rejection is made under 35 USC 103, obviousness standard.

The instant invention remains rejected for reasons of record.

Conclusion

No claims allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 10/17/05